

Notice of Allowability

Application No.

09/888,233

Examiner

Peter Paras, Jr.

Applicant(s)

BLAKELY ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the election received on 12/3/02.
2. ☒ The allowed claim(s) is/are 15-42, 44-52, and 56-64 (renumbered as 1-46).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. 0104.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ . |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No. <u>0102, 1202</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ . |

DETAILED ACTION

Applicant's amendment to the specification received on 10/27/03 has been entered. Claims 1-100 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 15-16, 21-28 and 43-64, in the response received on 12/3/02 is acknowledged. The traversal is on the ground(s) that claims directed to methods of screening should not be restricted with respect to the agents used in the screening process. Applicants submit that claims from Groups I-VII should be examined together. Applicant's arguments are found persuasive. The claims of Groups I-VII as well as generic claims 1-14, claims 1-64 in all, will be examined in the instant Office action.

The restriction requirement over Groups VIII-XI however is maintained. Applicant's arguments were directed to Groups I-VII only. Therefore requirement over Groups VIII-XI is still deemed proper and is therefore made FINAL.

Claims 66-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response received on 12/3/02.

Sequence Compliance

The amendment received on 10/27/03 has been entered. The instant application is now compliant with the sequence rules.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven Highlander on 1/21/04.

The specification has been amended as follows:

On page 19, in line 3, the term "http://" prior to the term "www.wormbase" has been deleted.

On page 43, in line 20, the term "http://" prior to the term "info.med.yale" has been deleted.

On page 47, in line 3, the term "http://" prior to "bgypc086" has been deleted.

On page 51, in line 18, the term "http://" prior to "www.elegans" has been deleted.

On page 54, in line 13, the term "http://" prior to "www.wormbase" has been deleted.

On page 56, in line 5, the term "http://" prior to "bgypc086" has been deleted.

The following has been inserted on page 11 of the specification beginning in line 9: The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

In the claims:

Claims 1-14, 43, 53-55, and 65-100 have been cancelled.

Claims 15, 27, 28, 44, 45 and 56-64 have been amended as follows:

15. A method of screening for substances that affect neuronal viability comprising:

- a) providing a recombinant *C. elegans* [that expresses a detectable marker in a neuronal cell] whose genome comprises a nucleotide sequence encoding a detectable marker operably linked to a neuronal specific promoter, wherein said marker is expressed in a neuronal cell;
- b) exposing said *C. elegans* to candidate substance; and
- c) detecting a change in the expression of the marker relative to the expression of the marker before said exposing; wherein a change in the expression of the marker corresponds to a change in the viability of said [the] neuronal cell.

27. The method of claim [15] 21, further comprising the step of exposing said *C. elegans* to a known neurotoxin prior to step b).

28. The method of claim [15] 21, further comprising the step of exposing said *C. elegans* to a known neurotoxin after to step b).

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44. The method of claim 15, wherein the change in marker expression can be an increase in [the] marker expression, wherein an increase in marker expression indicates that said substance increases viability of said neuronal cell.

45. The method of claim 15, wherein the change in marker expression can be a decrease in [the] marker expression, wherein a decrease in marker expression indicates that said substance decreases viability of said neuronal cell.

56. The method of claim [55] 15, wherein the neuronal-specific promoter is a dopamine transporter promoter.

57. The method of claim [55] 15, wherein the neuronal-specific promoter is a tyrosine hydroxylase promoter, a *cha-1* promoter, an *acr-2* promoter, an unc-30 promoter, an *unc-4* promoter, or an *asi* promoter.

58. The method of claim 15, wherein the neuronal cell [comprises] is a dopaminergic neuron.

59. The method of claim 15, wherein the neuronal cell [comprises] is a cholinergic neuron.

60. The method of claim 15, wherein the neuronal cell [comprises] is a GABA-ergic neuron.

61. The method of claim 15, wherein the neuronal cell [comprises] is a glycinergic neuron.

62. The method of claim 15, wherein the neuronal cell [comprises] is a serotonergic neuron.

63. The method of claim 15, wherein the neuronal cell [comprises] is a glutamatergic neuron.

64. The method of claim 15, wherein the neuronal cell [comprises] is a peptidergic neuron.

Drawings

New corrected drawings are required in this application because figure 1 contains handwritten text and because figures 1 and 3-6 appear to be photocopies that are illegible. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate. The required statement has been entered above as part of the Examiner's amendment. However, the required petition and fee are required.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Oath/Declaration

Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth below. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner. The signature of inventor David Miller is not present in the submitted declaration.

The following is an examiner's statement of reasons for allowance: The instantly claimed invention is allowable over the prior art because the prior art does not teach or fairly suggest methods of screening for substances that affect neuronal viability in a recombinant *C. elegans* expressing a marker in neuronal cell.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

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**PETER PARAS
PATENT EXAMINER**

A handwritten signature in cursive script, appearing to read "Pete Paras", written in black ink.